

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial Number : 10/518,223
Filing Date : 15 Dec 2004
In re Appl. of : Cheng, Ning Man *et al.*
Art Unit : 1652
Examiner : Dr. I. H. Chowdhury
Attorney Docket : B001.001.NPRUS

DECLARATION UNDER 37 C.F.R. §1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam,

We, Ning Man Cheng, Yun Chung Leung and Wai Hung Lo, (collectively, “the Applicants”) do declare and state as follows:

1. We are joint inventors of the subject matter which is described and now claimed in the above-identified application.
2. This declaration and its attachments were prepared to evidence reduction to practice of the invention of at least claim 28 of the above-identified application (*i.e.*, USSN 10/518,223), on a date before January 25, 2002, which is the earliest effective filing date of Tepic *et al.*, WO 03/063780 (PCT/US03/02342). Tepic *et al.* was cited by the Examiner in an Office Action dated July 27, 2007, as prior art to the instant application pursuant to 35 U.S.C. §102(e).
3. The invention described in claim 28 of the above-identified application was completed by us or under our supervision prior to January 25th, 2002 as documented in the laboratory notebook records (Exhibit A through Exhibit D) filed herewith. These activities, among

other activities, were carried out in Hong Kong, China, which has been a member of the World Trade Organization since January 1, 1995.

EVIDENTIARY EVIDENCE

4. Exhibit A shows laboratory records documenting the existence of a treatment protocol prior to the critical date that was used to administer a modified, full-length recombinant human arginase I polypeptide which was covalently linked to at least one polyethylene glycol (PEG) molecule to a human subject with rectal cancer as detailed in the specification of the instant application in Example 9A and Example 12. (see US 2005/0244398).

5. Exhibits B, C and D document that prior to the critical date, the Applicants had administered a modified, full-length recombinant human arginase I polypeptide according to the protocol of Exhibit A, which was covalently linked to at least one polyethylene glycol (PEG) molecule in a method to treat a malignancy (rectal cancer) in a human subject. These laboratory records document that prior to the critical date, the Applicants were in possession of the arginine concentration data (Exhibit B and Exhibit C) and the arginase activity data (Exhibit D) from the human subject which is presented graphically as FIGs. 21 and 28 in the application as filed, wherein the physiological arginine level in the human subject was reduced to below 10 μ M for at least 3 days. (See also, US 2005/0244398; Example 9A and 12).

6. We declare that the acts evidenced by Exhibit A, Exhibit B, Exhibit C, and Exhibit D, occurred prior to January 25, 2002.

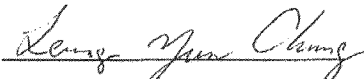
7. We declare that the subject matter which is described and now claimed in the above-identified application was pursued by the Applicants with due diligence from the acts evidenced by Exhibit A, Exhibit B, Exhibit C, and Exhibit D through to the filing date of the above-identified application.

8. We declare that all statements made herein of our own knowledge are true and that

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all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

26 Jan 08 
Date Ning Man Cheng

26 Jan 2008 
Date Yun Chung Leung

26 Jan 2008 
Date Wai Hung Lo

Recombinant human arginase in Treatment of Cancer

The day before arginase infusion, two blood samples were taken (before insulin infusion and after insulin infusion). The baseline level of amino acids and the activity of endogenous arginase were measured from these two samples.

Day 1

The first dosage of 50mg pegylated arginase was infused at 10:00 am in Day 1. After the first infusion, blood sample was taken and analyzed with the use of Amino Acid Analyzer at every two hours interval, amino acid profile and activity of arginase were measured

The second dosage of pegylated 50mg arginase was infused at 22:00 p.m. in Day 1 (12 hours after first infusion). Similarly, blood sample was taken and analyzed at every two hours after infusion.

Day 2

The third dosage of pegylated 50mg arginase was infused at 10:00 am in Day 2 (12 hours after second infusion). Blood sample was taken and analyzed at every four hours after infusion.

Day 2 – Day 7

Starting from 13:00 p.m. in Day 2 (3 hours after the third infusion), continuous infusion of 100mg/day arginase was used instead of infusion. Blood sample was taken and analyzed at every four hours after infusion. The continuous infusion was maintained until 13:00 p.m. in Day 7. Continuous infusion of 100mg arginase was stopped at 13:00 p.m. in Day 7

Day 7 – Day 10

After stopping arginase infusion, amino acid profile and the activity of the arginase were still monitored by taken blood sample in every 4 hour.

Day 11 –Day 20

One Single blood sample was taken in each day for monitoring the amino acid profile and the activity of arginase.

Day 21-Day 31

One single blood sample was taken every two days for monitoring the amino acid profile and the activity of the arginase.

EXHIBIT A
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Blood Sample collecting Schedule:

AA = amino acid profile analysis

Activity = activity test for arginase

Day before arginase infusion [REDACTED]	Day 1 [REDACTED]
10:00 a.m. (AA & activity) 16:00 p.m. insulin infusion 21:00 p.m. (AA)	06:00 am (AA) 10:00 a.m. first intermittent infusion, 50mg pegylated arginase in 50 ml PBS 11:00 a.m. (AA & activity) 14:00 p.m. (AA) 16:00 p.m. (AA) 18:00 p.m. (AA & activity) 20:00 p.m. (AA) 22:00 p.m. second intermittent infusion, 50mg pegylated arginase in 50 ml PBS 22:00 (AA)

Day 2 [REDACTED]	Day 3 – Day 6 [REDACTED]
00:00 a.m. (AA) 02:00 a.m. (AA & activity) 04:00 a.m. (AA) 06:00 a.m. (AA) 08:00 a.m. (AA) 10:00 a.m. third intermittent infusion, 50mg pegylated arginase in 50 ml PBS 10:00 a.m. (AA & activity) 13:00 p.m. continuous infusion start, 100 mg pegylated arginase / day 14:00 p.m. (AA) 18:00 p.m. (AA & activity) 22:00 p.m. (AA)	(Continuous infusion 100 mg pegylated arginase / day) 02:00 a.m. (AA & activity) 06:00 a.m. (AA) 10:00 a.m. (AA & activity) 14:00 p.m. (AA) 18:00 p.m. (AA & activity) 22:00 p.m. (AA)

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Day 7 [REDACTED]	Day 8- Day 10 [REDACTED]
<p align="center">(Continuous infusion 100 mg pegylated arginase / day)</p> <p>02:00 a.m. (AA & activity) 06:00 a.m. (AA) 10:00 a.m. (AA & activity)</p> <p align="center">Stop Continuous infusion</p> <p>14:00 p.m. (AA) 18:00 p.m. (AA & activity) 22:00 p.m. (AA)</p>	<p>02:00 a.m. (AA & activity) 06:00 a.m. (AA) 10:00 a.m. (AA & activity) 14:00 p.m. (AA) 18:00 p.m. (AA & activity) 22:00 p.m. (AA)</p>
Day 11 – Day 20 [REDACTED]	Day 21- Day 31 [REDACTED]
<p>10:00 a.m. (AA & activity)</p>	<p>AA & Activity was monitored in every two day</p>

EXHIBIT A
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Labeling.	Patient Name	Date	Remarks
1	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level, baseline
1.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30min
1.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 1hr
1.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 2hr
2	Mrs. A [REDACTED]	[REDACTED] 21:00	Arginine level
3	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
First infusion 10:00 50mg pegylated arginase in 50 ml PBS			
4	Mrs. A [REDACTED]	[REDACTED] 11:00	Arginine level
4.0	Mrs. A [REDACTED]	[REDACTED] 11:00	Activity, 0mins
4.1	Mrs. A [REDACTED]	[REDACTED] 11:00	Activity, 10mins
4.2	Mrs. A [REDACTED]	[REDACTED] 11:00	Activity, 30mins
4.3	Mrs. A [REDACTED]	[REDACTED] 11:00	Activity, 60mins
5	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
6	Mrs. A [REDACTED]	[REDACTED] 16:00	Arginine level
7	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
7.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
7.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
7.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
7.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
Second infusion 22:00 50mg pegylated arginase in 50 ml PBS			
8	Mrs. A [REDACTED]	[REDACTED] 20:00	Arginine level
9	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
10	Mrs. A [REDACTED]	[REDACTED] 00:00	Arginine level
11	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
11.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
11.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
11.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
11.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins
12	Mrs. A [REDACTED]	[REDACTED] 04:00	Arginine level

EXHIBIT A
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Thursday [REDACTED]

Labeling.	Patient Name	Date	Remarks
13	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
14	Mrs. A [REDACTED]	[REDACTED], 08:00	Arginine level
Third infusion 10:00 50mg pegylated arginase in 50 ml PBS			
15	Mrs. A [REDACTED]	[REDACTED], 10:00	Arginine level
15.0	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 0mins
15.1	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 10mins
15.2	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 30mins
15.3	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 60mins
Continuous infusion 100mg/days 13:00			
16	Mrs. A [REDACTED]	[REDACTED], 14:00	Arginine level
17.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
17.1	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 10mins
17.2	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 30mins
17.3	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 60mins
18	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
19	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
19.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
19.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
19.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
19.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins

EXHIBIT A
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Friday [REDACTED]

Labeling.	Patient Name	Date	Remarks
20	Mrs. A [REDACTED]	[REDACTED], 06:00	Arginine level
21	Mrs. A [REDACTED]	[REDACTED], 10:00	Arginine level
21.0	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 0mins
21.1	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 10mins
21.2	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 30mins
21.3	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 60mins
22	Mrs. A [REDACTED]	[REDACTED], 14:00	Arginine level
23	Mrs. A [REDACTED]	[REDACTED], 18:00	Arginine level
23.0	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 0mins
23.1	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 10mins
23.2	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 30mins
23.3	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 60mins
24	Mrs. A [REDACTED]	[REDACTED], 2200	Arginine level
25	Mrs. A [REDACTED]	[REDACTED], 0200	Arginine level
25.0	Mrs. A [REDACTED]	[REDACTED], 0200	Activity, 0mins
25.1	Mrs. A [REDACTED]	[REDACTED], 0200	Activity, 10mins
25.2	Mrs. A [REDACTED]	[REDACTED], 0200	Activity, 30mins
25.3	Mrs. A [REDACTED]	[REDACTED], 0200	Activity, 60mins

EXHIBIT A
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Saturday [REDACTED]

Labeling.	Patient Name	Date	Remarks
26	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
27	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
28	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
28.0	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 0mins
28.1	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 10mins
28.2	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 30mins
28.3	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 60mins
29	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
30	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
30.0	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 0mins
30.1	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 10mins
30.2	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 30mins
30.3	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 60mins
31	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
31.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
31.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
31.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
31.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins

EXHIBIT A
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Sunday [REDACTED]

Labeling.	Patient Name	Date	Remarks
32	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
33	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
33.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
33.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
33.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
33.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
34	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
35	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
35.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
35.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
35.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
35.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
36	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
37	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
37.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
37.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
37.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
37.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins

EXHIBIT A
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Monday [REDACTED]

Labeling.	Patient Name	Date	Remarks
38	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
39	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
39.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
39.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
39.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
39.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
40	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
41	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
41.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
41.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
41.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
41.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
42	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
43	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
43.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
43.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
43.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
43.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins

EXHIBIT A
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Tuesday [REDACTED]

Labeling.	Patient Name	Date	Remarks
44	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
45	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
45.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
45.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
45.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
45.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
46	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
47	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
47.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
47.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
47.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
47.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
48	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
49	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
49.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
49.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
49.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
49.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins

EXHIBIT A
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Wednesday [REDACTED]

Labeling.	Patient Name	Date	Remarks
50	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
51	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
51.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
51.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
51.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
51.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
52	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
53	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
53.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
53.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
53.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
53.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
54	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
54.0	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 0mins
54.1	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 10mins
54.2	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 30mins
54.3	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 60mins
55	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
55.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
55.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
55.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
55.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins

EXHIBIT A
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Thursday [REDACTED]

Labeling.	Patient Name	Date	Remarks
56	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
56.0	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 0mins
56.1	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 10mins
56.2	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 30mins
56.3	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 60mins
57	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
57.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
57.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
57.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
57.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
58	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
58.0	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 0mins
58.1	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 10mins
58.2	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 30mins
58.3	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 60mins
59	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
59.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
59.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
59.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
59.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
60	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
60.0	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 0mins
60.1	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 10mins
60.2	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 30mins
60.3	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 60mins
61	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
61.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
61.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
61.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
61.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins

EXHIBIT A
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Friday [REDACTED]

Labeling.	Patient Name	Date	Remarks
62	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
62.0	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 0mins
62.1	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 10mins
62.2	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 30mins
62.3	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 60mins
63	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
63.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
63.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
63.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
63.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
64	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
64.0	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 0mins
64.1	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 10mins
64.2	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 30mins
64.3	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 60mins
65	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
65.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
65.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
65.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
65.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
66	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
66.0	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 0mins
66.1	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 10mins
66.2	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 30mins
66.3	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 60mins

EXHIBIT A
USSN 10/518,223

Saturday [REDACTED]			
Labeling.	Patient Name	Date	Remarks
67	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
67.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
67.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
67.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
67.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
Sunday [REDACTED]			
68	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
68.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
68.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
68.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
68.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
Monday [REDACTED]			
69	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
69.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
69.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
69.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
69.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
70	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
70.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
70.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
70.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
70.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
Tuesday [REDACTED]			
71	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
71.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
71.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
71.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
71.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins

EXHIBIT A
USSN 10/518,223

Wednesday, [REDACTED]			
72	Mrs. A [REDACTED]	[REDACTED], 10:00	Arginine level
72.0	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 0mins
72.1	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 10mins
72.2	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 30mins
72.3	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 60mins
Thursday, [REDACTED]			
73	Mrs. A [REDACTED]	[REDACTED], 10:00	Arginine level
73.0	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 0mins
73.1	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 10mins
73.2	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 30mins
73.3	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 60mins
Friday, [REDACTED]			
74	Mrs. A [REDACTED]	[REDACTED], 10:00	Arginine level
74.0	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 0mins
74.1	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 10mins
74.2	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 30mins
74.3	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 60mins
Saturday, [REDACTED]			
75	Mrs. A [REDACTED]	[REDACTED], 10:00	Arginine level
75.0	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 0mins
75.1	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 10mins
75.2	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 30mins
75.3	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 60mins
Sunday, [REDACTED]			
76	Mrs. A [REDACTED]	[REDACTED], 10:00	Arginine level
76.0	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 0mins
76.1	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 10mins
76.2	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 30mins
73.3	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 60mins

EXHIBIT A
USSN 10/518,223

Monday, [REDACTED]			
77	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
77.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
77.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
77.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
77.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
Wednesday, [REDACTED]			
78	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
78.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
78.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
78.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
78.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
Friday, [REDACTED]			
79	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
79.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
79.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
79.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
79.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
Monday [REDACTED]			
80	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
80.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
80.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
80.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
80.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
Wednesday [REDACTED]			
81	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
81.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
81.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
81.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
81.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0013

Report Name: original

L-8800 AAA System Manager Report

Analyzed: 05:56 PM

Series: 0013

Sample Name: 45.2

Injection from this vial: 1 of 1

Reported: 07:53 PM

Vial Number: 54

Vial Type: UNK

Volume: 20.0 ul

Sample Description: 45.2, activity, 30mins

Chrom Type: AAA Channel : 1

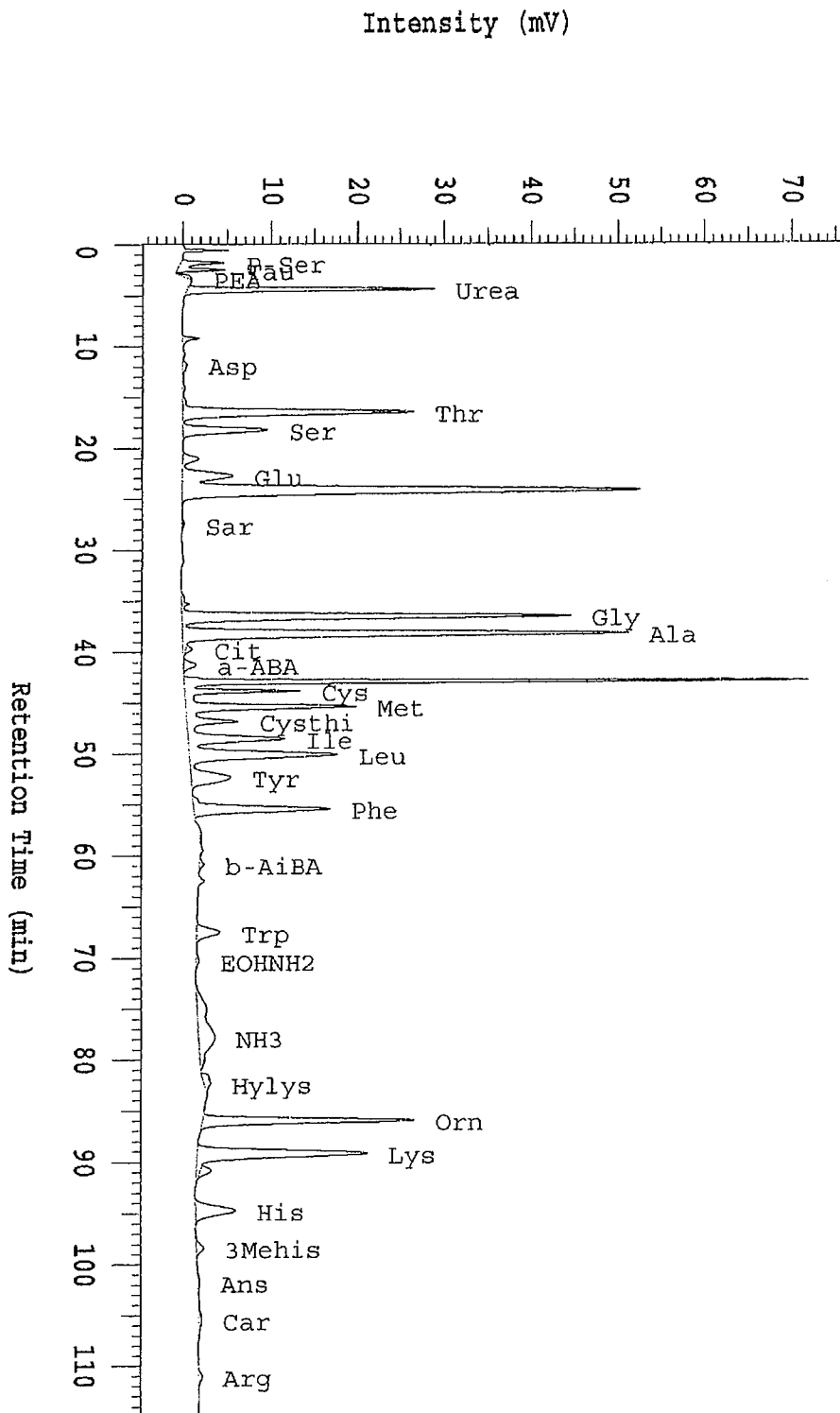


EXHIBIT B

USSN 10/518,223

L-8800 ASM: PF
 Analyzed: 05:56 PM
 Reported: 07:53 PM
 Series: 0013
 Vial Number: 54
 Volume: 20.0 uL
 Sample Name: 45.2
 Vial Type: UNK
 Report Name: original
 Scale Factor 1: 1.000

No.	RT	Name	Height	Area	Conc 1 mmol	Conc 2 ng	Peak Ratio
1	1.79	P-Ser	4949	95466	0.167	30.843	0.0
2	2.48	Tau	5506	85923	0.193	24.104	0.0
3	3.29	PEA	476	19923	0.056	7.887	0.0
4	4.42	Urea	28454	577315	55.336	3325.669	0.0
5	9.19		1933	40660	0.000	0.000	0.0
6	10.75		261	11117	0.000	0.000	0.0
7	11.79	Asp	570	30519	0.055	7.360	0.0
8	14.05		241	12808	0.000	0.000	0.0
9	15.41		423	15809	0.000	0.000	0.0
10	16.49	Thr	26595	916897	1.497	178.244	0.0
11	18.24	Ser	9619	344008	0.568	59.737	0.0
12	21.05		1822	76844	0.000	0.000	0.0
13	22.75	Glu	5775	290309	0.547	80.519	0.0
14	24.17		52577	2201585	0.000	0.000	0.0
15	27.52	Sar	254	10330	0.080	7.167	0.0
16	34.67		398	16499	0.000	0.000	0.0
17	35.21		936	17945	0.000	0.000	0.0
18	36.49	Gly	44719	1408983	2.414	181.257	0.0
19	38.19	Ala	51252	1783653	2.898	258.229	0.0
20	39.65	Cit	766	24768	0.042	7.435	0.0
21	41.23	a-ABA	1423	58616	0.096	9.860	0.0
22	42.89		71752	1281031	0.000	0.000	0.0
23	43.81	Cys	13204	260037	0.396	95.063	0.0
24	45.35	Met	19604	608281	0.949	141.615	0.0
25	46.79	Cysthi	5858	214842	0.274	60.842	0.0
26	48.52	Ile	11000	450297	0.710	93.178	0.0
27	50.09	Leu	16976	762310	1.231	161.493	0.0
28	52.31	Tyr	4486	297006	0.506	91.703	0.0
29	55.45	Phe	15538	611870	1.051	173.671	0.0
30	60.87	b-AlBA	579	21462	0.078	8.033	0.0
31	67.48	Tyr	2658	144870	0.000	0.000	0.0
32	70.31	BOHMH2	354	25655	0.065	3.944	0.0
33	75.05		1075	122594	0.000	0.000	0.0
34	77.83	NH3	1850	326773	0.618	10.512	0.0
35	79.93		171	12096	0.000	0.000	0.0
36	82.33	Hyllys	791	63931	0.102	16.548	0.0
37	85.99	Orn	24429	806655	1.256	165.982	0.0
38	89.19	Lys	19545	944985	1.536	224.609	0.0
39	90.81		1238	55800	0.000	0.000	0.0
40	94.73	His	4600	281147	0.460	71.340	0.0
41	98.36	3Mehis	826	46854	0.079	13.289	0.0
42	101.72	Ans	211	15564	0.110	26.389	0.0
43	105.45	Car	313	36454	0.150	33.973	0.0
44	111.00	Arg	433	24059	0.044	7.602	0.0
			456440	15459550	73.562	5578.097	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0013

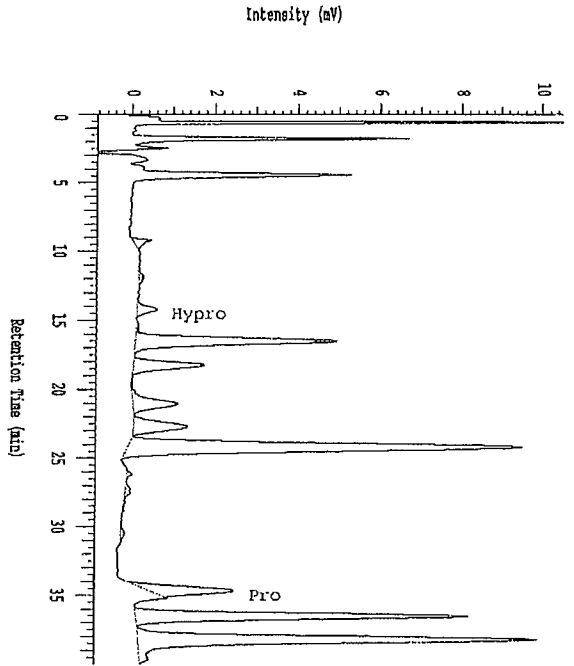
Report Name: original

L-8800 AAA System Manager Report

Analyzed: 05:56 PM
Chrom Type: AAA Channel : 2

Reported: 07:53 PM

Series: 0013
Vial Number: 54
Vial Type: UNK
Volume: 20.0 ul
Injection from this vial: 1 of 1
Sample Name: 45.2
Sample Description: 45.2, activity, 30mins
Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	9.20		462	10479	0.000	0.000	0.0
2	14.20	Hypro	497	15959	0.186	24.447	0.0
3	16.49		4871	169603	0.000	0.000	0.0
4	18.24		1727	61889	0.000	0.000	0.0
5	21.03		1102	48560	0.000	0.000	0.0
6	22.65		1311	57965	0.000	0.000	0.0
7	24.19		9640	384613	0.000	0.000	0.0
8	34.67	Pro	2046	76193	0.655	75.420	0.0
9	36.51		8083	249371	0.000	0.000	0.0
10	38.20		9751	353120	0.000	0.000	0.0
			39490	1427752	0.842	99.867	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0014

Report Name: original

L-8800 AAA System Manager Report

Analyzed: 09:57 AM

Reported: 11:53 AM

Series: 0014

Vial Number: 62

Sample Name: 49.2

Vial Type: UNK

Injection from this vial: 1 of 1

Volume: 20.0 ul

Sample Description:

02:00, t30

Chrom Type: AAA Channel : 1

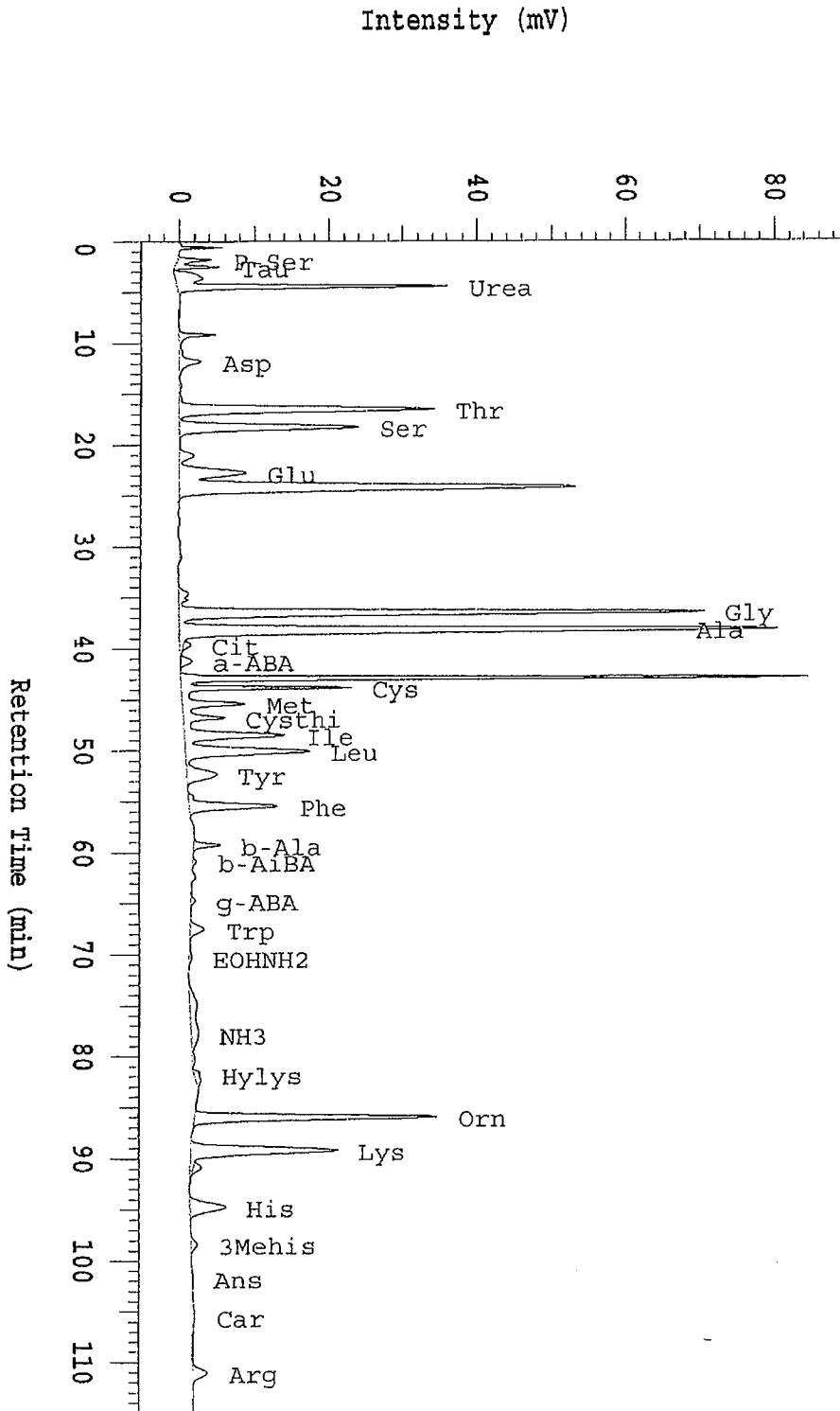


EXHIBIT B

USSN 10/518,223

L-8800 ASM: PF				Series: 0014		Report Name: original	
Analyzed:	09:57 AM	Vial Number: 62	Sample Name:			49.2	
Reported:	11:53 AM	Volume: 20.0 u1	Vial Type: UNK				Scale Factor 1: 1.000
No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	1.79	P-Ser	4573	91522	0.160	29.568	0.0
2	2.49	Tau	6084	91775	0.206	25.746	0.0
3	3.62		3720	199524	0.000	0.000	0.0
4	4.43	Urea	36459	769049	73.713	4430.166	0.0
5	9.17		5021	100394	0.000	0.000	0.0
6	11.79	Asp	3013	152429	0.276	36.760	0.0
7	14.13		342	18826	0.000	0.000	0.0
8	16.48	Thr	34341	1215392	1.984	236.271	0.0
9	18.24	Ser	24038	881366	1.456	153.048	0.0
10	21.04		1990	91127	0.000	0.000	0.0
11	22.75	Glu	8979	457429	0.862	126.871	0.0
12	24.17		53168	2241240	0.000	0.000	0.0
13	34.63		1275	55207	0.000	0.000	0.0
14	35.19		1227	23640	0.000	0.000	0.0
15	36.48	Gly	70599	2235727	3.830	287.613	0.0
16	38.16	Ala	80290	2815498	4.575	407.615	0.0
17	39.60	Cit	993	32626	0.056	9.793	0.0
18	41.19	a-ABA	1497	62438	0.102	10.502	0.0
19	42.88		84322	1511996	0.000	0.000	0.0
20	43.80	Cys	22762	432102	0.657	157.966	0.0
21	45.35	Met	8430	293564	0.458	68.345	0.0
22	46.73	Cysthi	5535	210202	0.268	59.528	0.0
23	48.47	Ile	13435	542534	0.856	112.265	0.0
24	50.04	Leu	16683	758954	1.225	160.782	0.0
25	52.31	Tyr	4069	270311	0.461	83.461	0.0
26	54.52		735	18594	0.000	0.000	0.0
27	55.43	Phe	11847	462460	0.795	131.263	0.0
28	59.27	b-Ala	3592	100893	0.317	28.249	0.0
29	60.87	b-AIBA	579	18899	0.069	7.073	0.0
30	64.68	G-ABA	648	27777	0.047	4.801	0.0
31	67.48	Tyr	2003	108802	0.000	0.000	0.0
32	70.28	BOHNE2	380	29128	0.073	4.478	0.0
33	75.00		1047	129497	0.000	0.000	0.0
34	77.83	NH3	1072	166117	0.314	5.344	0.0
35	80.41		388	28634	0.000	0.000	0.0
36	81.75	Hylys	825	28548	0.046	7.390	0.0
37	82.33		805	36931	0.000	0.000	0.0
38	85.99	Orn	32615	1090145	1.697	224.314	0.0
39	89.21	Lys	19642	965688	1.562	228.321	0.0
40	90.84		1154	52340	0.000	0.000	0.0
41	94.73	His	4740	295496	0.483	74.981	0.0
42	98.39	3Mehis	900	52198	0.087	14.805	0.0
43	101.69	Ans	185	11932	0.084	20.231	0.0
44	105.53	Car	262	23296	0.096	21.711	0.0
45	111.03	Arg	2016	112151	0.203	35.436	0.0
Peak rejection level: 10000			578280	19317398	97.017	7204.697	

EXHIBIT B **USSN 10/518,223**

L-8800 ASM: PF

Series: 0014

Report Name: original

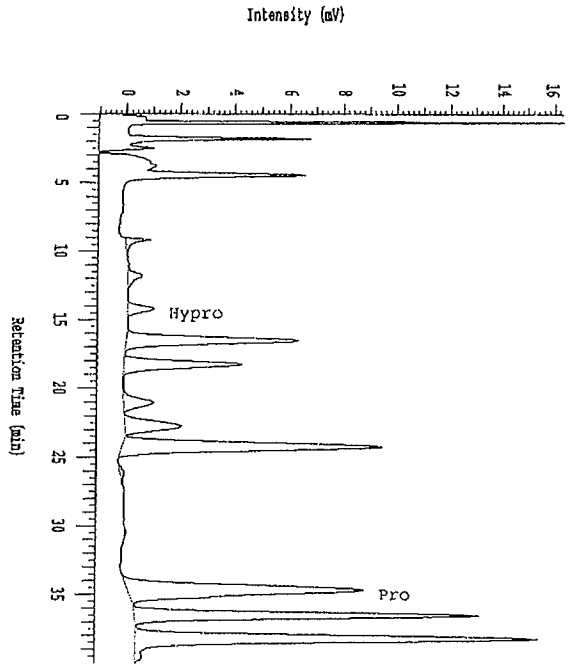
L-8800 AAA System Manager Report

Analyzed: 09:57 AM

Chrom Type: AAA Channel : 2

Reported: 11:53 AM

Series: 0014
Vial Number: 62
Vial Type: UNK
Volume: 20.0 uL
Injection from this vial: 1 of 1
Sample Name: 49.2
Sample Description: 49.2, 02:00, t30
Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	9.17		952	18216	0.000	0.000	0.0
2	11.77		566	25716	0.000	0.000	0.0
3	14.19	Hypro	993	32907	0.384	50.406	0.0
4	16.49		6353	220719	0.000	0.000	0.0
5	18.24		4381	158764	0.000	0.000	0.0
6	21.00		1143	49337	0.000	0.000	0.0
7	22.71		2101	96229	0.000	0.000	0.0
8	24.19		9620	384761	0.000	0.000	0.0
9	34.63	Pro	8757	432842	3.722	428.454	0.0
10	36.48		12832	397636	0.000	0.000	0.0
11	38.17		15061	539866	0.000	0.000	0.0
			62759	2356993	4.107	478.861	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0016

Report Name: original

L-8800 AAA System Manager Report

Analyzed: 06:09 PM

Series: 0016

Reported: 08:06 PM

Vial Number: 5

Sample Name: 52.2

Vial Type: UNK

Injection from this vial: 1 of 1

Volume: 20.0 uL

Sample Description: 52.2, activity, 30mins

Chrom Type: AAA Channel : 1

14:00

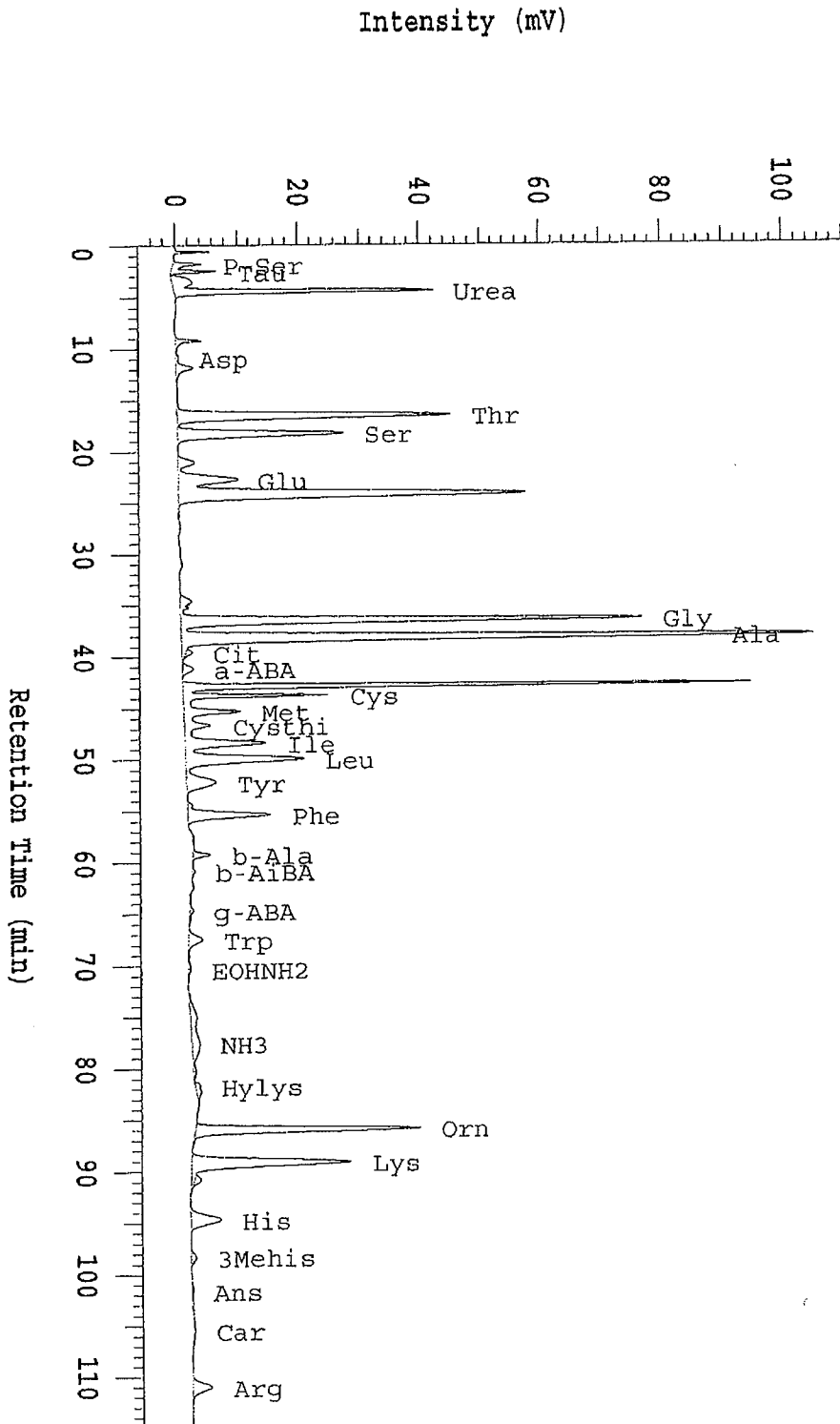


EXHIBIT B

USSN 10/518,223

L-8800 ASM: PF			Series: 0016			Report Name: original		
Analyzed:	06:09 PM		Vial Number: 5		Sample Name:			
Reported:	08:06 PM		Volume: 20.0 uL		Vial Type: UNK			
No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Scale Factor 1: 1.000	Peak Ratio
1	1.78	P-Ser	4571	86670	0.151	28.001		0.0
2	2.48	Tau	7502	107441	0.241	30.141		0.0
3	3.61		3266	181169	0.000	0.000		0.0
4	4.42	Urea	42482	872545	83.633	5026.363		0.0
5	9.20		4272	82490	0.000	0.000		0.0
6	10.83	Asp	429	16684	0.030	4.024		0.0
7	11.81		2639	114735	0.000	0.000		0.0
8	14.16		301	15652	0.000	0.000		0.0
9	16.49	Thr	45047	1571300	2.565	305.459		0.0
10	18.24	Ser	27172	985414	1.628	171.116		0.0
11	21.03		2703	120796	0.000	0.000		0.0
12	22.72	Glu	9735	496625	0.936	137.742		0.0
13	24.16		57265	2404042	0.000	0.000		0.0
14	34.59		1748	78333	0.000	0.000		0.0
15	35.20		1310	25192	0.000	0.000		0.0
16	36.45	Gly	76148	2393178	4.099	307.868		0.0
17	38.13	Ala	104243	3603653	5.855	521.720		0.0
18	39.52	Cit	1071	33795	0.058	10.144		0.0
19	41.12	a-ABA	1692	69848	0.114	11.749		0.0
20	42.83		93665	1654060	0.000	0.000		0.0
21	43.73	Cys	23796	457157	0.695	167.126		0.0
22	45.27	Met	9336	320177	0.500	74.541		0.0
23	46.63	Cyschi	4414	187730	0.239	53.164		0.0
24	48.36	Ile	13249	546016	0.861	112.985		0.0
25	49.93	Ieu	19412	886560	1.432	187.815		0.0
26	52.15	Tyr	4959	325823	0.555	100.601		0.0
27	54.41		782	21937	0.000	0.000		0.0
28	55.35	Phe	13537	530427	0.911	150.554		0.0
29	59.21	b-Ala	2992	81427	0.256	22.799		0.0
30	60.81	b-AlBA	565	19475	0.071	7.289		0.0
31	62.39		327	10657	0.000	0.000		0.0
32	64.63	g-ABA	548	21596	0.036	3.733		0.0
33	67.43	Tyr	2291	125777	0.000	0.000		0.0
34	70.28	EOHNM2	426	29534	0.074	4.541		0.0
35	75.00		1101	128164	0.000	0.000		0.0
36	77.51	NH3	1340	208850	0.395	6.719		0.0
37	80.25		426	30839	0.000	0.000		0.0
38	81.69	Hylys	878	30064	0.048	7.782		0.0
39	82.31		860	40029	0.000	0.000		0.0
40	85.93	Orn	36958	1231132	1.916	253.324		0.0
41	89.13	Iys	26093	1270732	2.055	300.444		0.0
42	90.79		1190	52472	0.000	0.000		0.0
43	94.65	His	5064	313650	0.513	79.587		0.0
44	98.28	3MeHis	853	45931	0.077	13.027		0.0
45	101.53	Ans	180	11678	0.082	19.800		0.0
46	105.40	Car	292	25984	0.107	24.216		0.0
47	110.95	Arg	3267	185577	0.337	58.636		0.0
			662457	22053017	110.472	8203.009		

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF
Peak rejection level: 10000

Series: 0016

Report Name: original

EXHIBIT B **USSN 10/518,223**

L-8800 ASM: PF

Series: 0016

Report Name: original

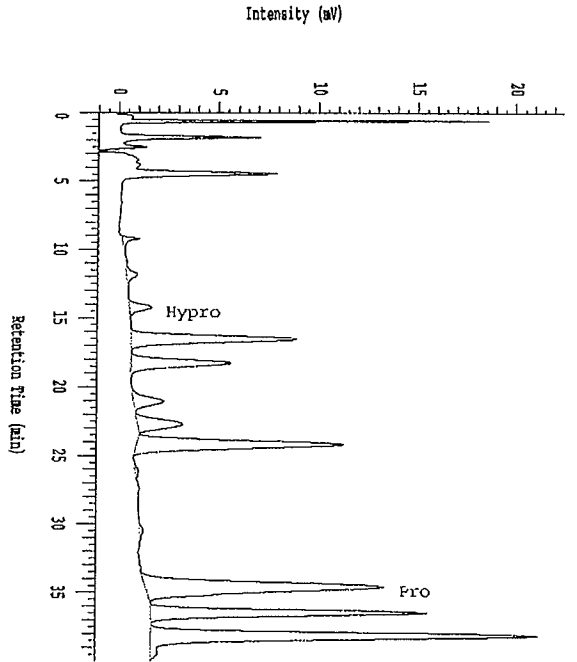
L-8800 AAA System Manager Report

Analyzed: 06:09 PM

Reported: 08:06 PM

Chrom Type: AAA Channel : 2

Series: 0016
Vial Number: 5
Vial Type: UNK
Volume: 20.0 u1
Injection from this vial: 1 of 1
Sample Name: 52.2
Sample Description: 52.2, activity, 30mins
Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 mmol	Conc 2 ng	Peak Ratio
1	9.21		896	18527	0.000	0.000	0.0
2	11.87		545	27741	0.000	0.000	0.0
3	14.24	Hypro	1139	37489	0.438	57.425	0.0
4	16.51		8284	283627	0.000	0.000	0.0
5	18.24		4994	180599	0.000	0.000	0.0
6	21.03		1540	65456	0.000	0.000	0.0
7	22.71		2292	102907	0.000	0.000	0.0
8	24.16		10362	412169	0.000	0.000	0.0
9	34.59	Pro	590879	590879	5.082	584.889	0.0
10	36.47		13894	428085	0.000	0.000	0.0
11	38.13		19583	693153	0.000	0.000	0.0
			75503	2840632	5.520	642.314	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0019

Report Name: original

L-8800 AAA System Manager Report

Analyzed: 02:13 PM

Series: 0019

Sample Name: 67.2

Injection from this vial: 1 of 1

Reported: 04:09 PM

Vial Number: 32

Vial Type: UNK

Volume: 20.0 uL

Sample Description:

67.2, 1000, t30

Chrom Type: AAA Channel : 1

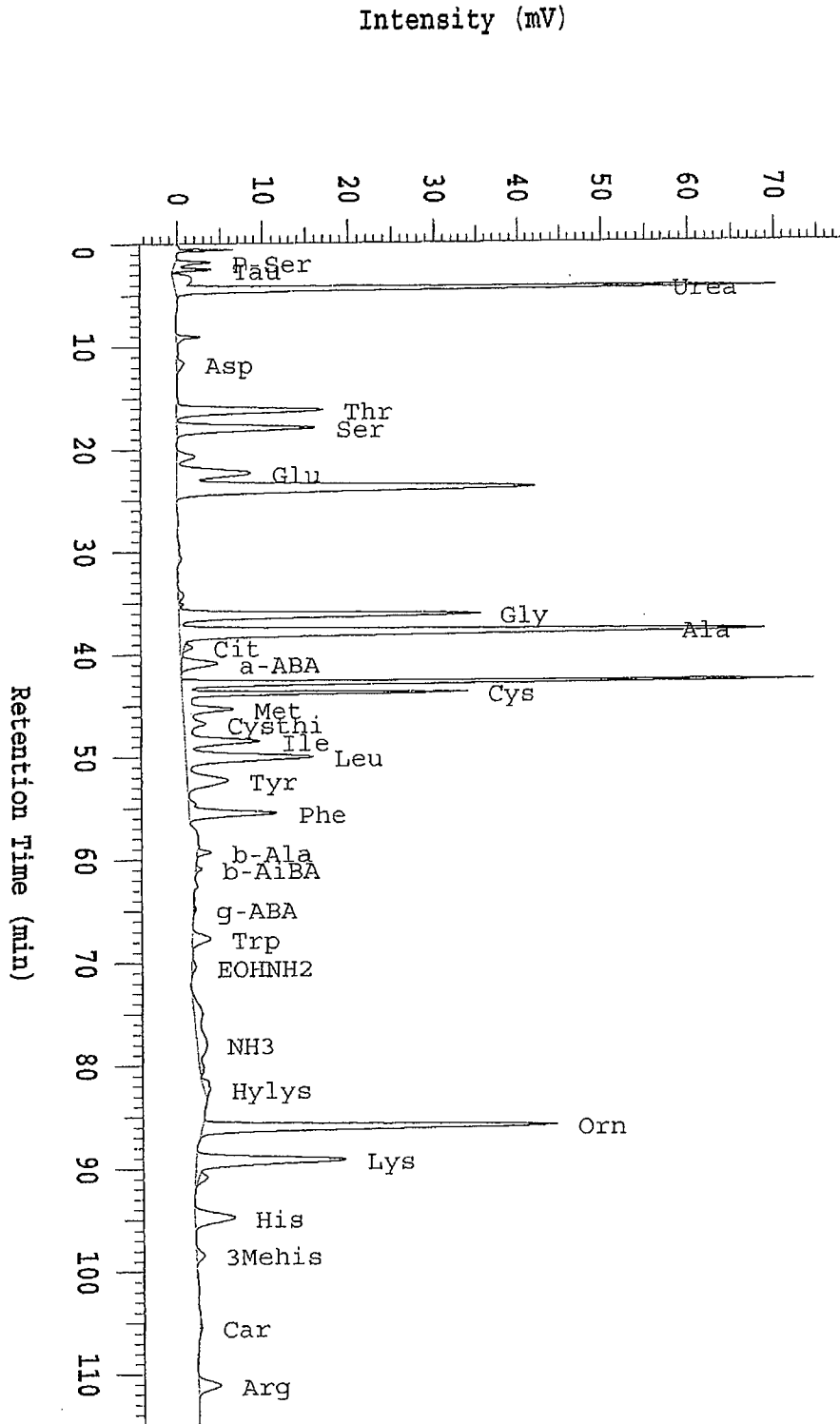


EXHIBIT B

USSN 10/518,223

L-8800 ASM: PF
 Analyzed: 02:13 PM
 Reported: 04:09 PM
 Series: 0019
 Sample Name: 32
 Vial Number: 32
 Volume: 20.0 ul
 Sample Name: UNK
 Vial Type: UNK
 Report Name: original
 Scale Factor 1: 1.000
 Scale Factor 2: 1.000

No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	1.79	P-Sex	4154	81624	0.142	26.371	0.0
2	2.49	Tau	4552	70105	0.157	19.667	0.0
3	3.57	Urea	2181	127590	0.000	0.000	0.0
4	4.39	Urea	70506	1506896	144.436	8680.589	0.0
5	9.04	Asp	2842	59340	0.000	0.000	0.0
6	11.59	Thr	937	61642	0.112	14.866	0.0
7	16.21	Ser	17135	614754	1.003	119.508	0.0
8	17.93	Ser	16232	600725	0.993	104.315	0.0
9	20.68	Glu	2183	96163	0.000	0.000	0.0
10	22.33	Glu	8752	456835	0.861	126.706	0.0
11	23.81		42242	1912085	0.000	0.000	0.0
12	30.67		324	13932	0.000	0.000	0.0
13	34.21		706	32855	0.000	0.000	0.0
14	35.07	Gly	672	12163	0.000	0.000	0.0
15	36.17	Ala	35411	1142964	1.958	147.035	0.0
16	37.84	Ala	68648	2457454	3.993	355.779	0.0
17	39.24	Cit	966	30871	0.053	9.267	0.0
18	40.84	a-ABA	4287	185576	0.303	31.215	0.0
19	42.79		74200	1384859	0.000	0.000	0.0
20	43.79	Cys	33503	619670	0.943	226.537	0.0
21	45.32	Met	6002	239579	0.374	55.777	0.0
22	46.73	Cysthi	2575	148314	0.189	42.002	0.0
23	48.47	Ile	8863	382794	0.604	79.210	0.0
24	50.04	Leu	14947	699952	1.130	148.283	0.0
25	52.28	Tyr	4840	326206	0.556	100.719	0.0
26	54.57		899	27240	0.000	0.000	0.0
27	55.51	Phe	103163	412163	0.708	116.987	0.0
28	59.29	b-Ala	1674	47716	0.150	13.360	0.0
29	60.92	b-AlBA	735	21552	0.078	8.066	0.0
30	64.76	G-ABA	292	10764	0.018	1.861	0.0
31	67.64	Trp	2160	122951	0.000	0.000	0.0
32	70.39	EOHMH2	517	37329	0.094	5.739	0.0
33	74.89		980	114877	0.000	0.000	0.0
34	77.93	NH3	1163	178624	0.338	5.746	0.0
35	80.28		471	34947	0.000	0.000	0.0
36	82.28	Hylys	808	65280	0.104	16.898	0.0
37	85.99	Lys	41910	1437624	2.238	295.813	0.0
38	89.21	Lys	17574	886410	1.433	209.577	0.0
39	90.84		1002	45107	0.000	0.000	0.0
40	94.76	His	4732	302734	0.495	76.817	0.0
41	98.39	3Mehis	954	56960	0.095	16.155	0.0
42	105.40	Car	254	20481	0.084	19.087	0.0
43	111.08	Arg	2668	154587	0.280	48.844	0.0

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0019

Report Name: original

L-8800 AA System Manager Report

Analyzed: 02:13 PM

Reported: 04:09 PM

Chrom Type: AAA Channel : 2

Series: 0019

Vial Number: 32

Vial Type: UNK

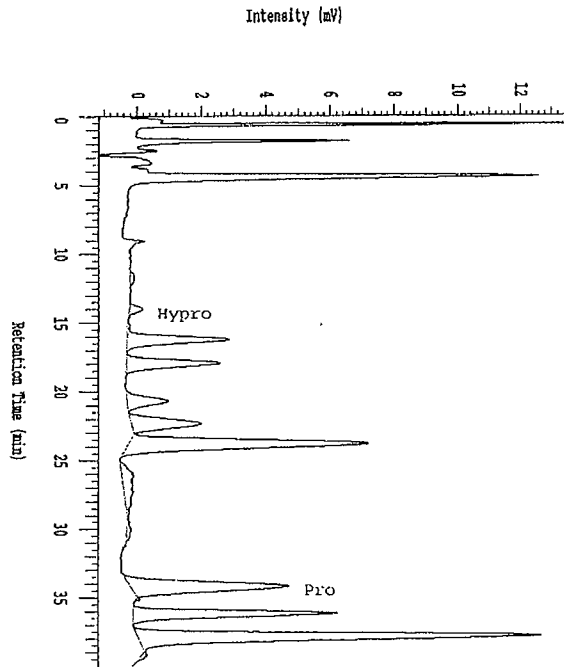
Volume: 20.0 uL

Injection from this vial: 1 of 1

Sample Name: 67.2

Sample Description: 67.2, 1000, t30

Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	14.00	Hypro	426	12889	0.151	19.744	0.0
2	16.23		3174	113962	0.000	0.000	0.0
3	17.95		2914	106122	0.000	0.000	0.0
4	20.71		1272	53464	0.000	0.000	0.0
5	22.33		2202	99498	0.000	0.000	0.0
6	23.81		7478	318313	0.000	0.000	0.0
7	26.15		379	49617	0.000	0.000	0.0
8	34.20	Pro	4910	227219	1.954	224.916	0.0
9	36.19		6358	200373	0.000	0.000	0.0
10	37.85		12670	447512	0.000	0.000	0.0
			41783	1628969	2.105	244.660	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0020

Report Name: original

L-8800 AAA System Manager Report

Analyzed: 02:38 PM

Reported: 04:34 PM

Series: 0020

Vial Number: 42

Sample Name: 68.2

Vial Type: UNK

Injection from this vial: 1 of 1

Volume: 20.0 ul

Sample Description:

68.2,
10:00

Chrom Type: AAA Channel : 1

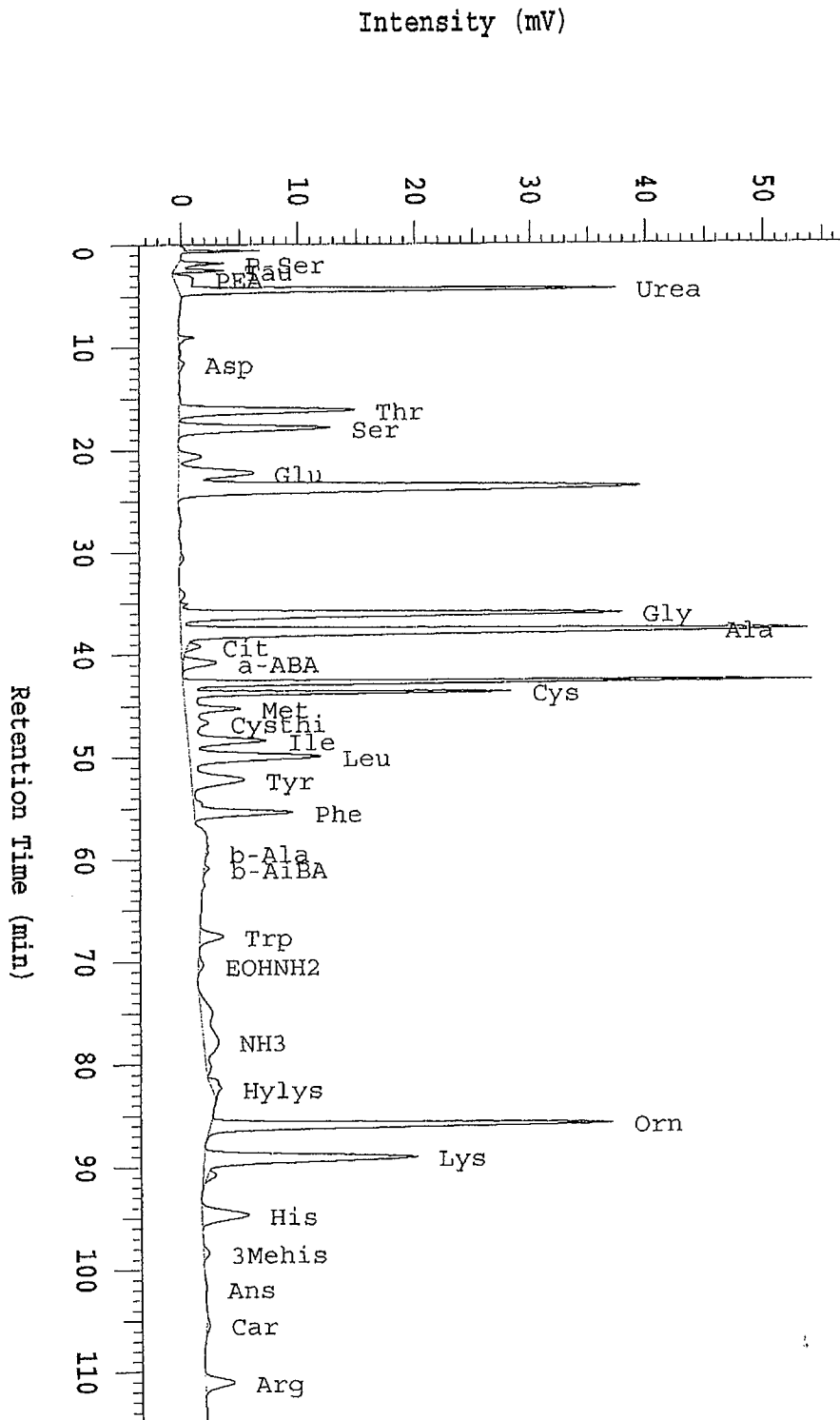


EXHIBIT B **USSN 10/518,223**

L-8800 ASM: PF			Series: 0020			Report Name: original		
Analyzed: 02:38 PM			Vial Number: 42			Sample Name: 68.2		
Reported: 04:34 PM			Volume: 20.0 uL			Vial Type: UNK		
No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Scale Factor 1: 1.000	Peak Ratio
1	1.79	P-Ser	3931	75773	0.132	24.480		0.0
2	2.50	Tau	4327	66741	0.150	18.723		0.0
3	3.25	PEA	1703	98486	0.276	38.984		0.0
4	4.40	Urea	37662	811459	77.778	4674.472		0.0
5	9.01		1355	36751	0.000	0.000		0.0
6	11.53	Asp	473	20928	0.038	5.047		0.0
7	16.16	Thr	15050	541345	0.884	105.237		0.0
8	17.88	Ser	12975	485852	0.803	84.368		0.0
9	20.61		1987	87827	0.000	0.000		0.0
10	22.25	Glu	6472	337580	0.637	93.630		0.0
11	23.75		39830	1832812	0.000	0.000		0.0
12	30.61		335	16128	0.000	0.000		0.0
13	34.11		504	23862	0.000	0.000		0.0
14	35.05		680	11557	0.000	0.000		0.0
15	36.12	Gly	38090	1244236	2.131	160.063		0.0
16	37.79	Ala	53771	1954338	3.176	282.940		0.0
17	39.16	Cit	1180	37956	0.065	11.393		0.0
18	40.76	a-ABA	2888	126744	0.207	21.319		0.0
19	42.75		53969	1027006	0.000	0.000		0.0
20	43.73	Cys	28105	531679	0.809	194.369		0.0
21	45.21	Met	4805	196255	0.306	45.691		0.0
22	46.60	Cysthi	1953	131851	0.168	37.340		0.0
23	48.36	Ile	6738	303448	0.479	62.791		0.0
24	49.96	Leu	11323	544532	0.879	115.357		0.0
25	52.15	Tyr	4617	308319	0.525	95.196		0.0
26	54.49		821	25565	0.000	0.000		0.0
27	55.40	Phe	8497	339849	0.584	96.462		0.0
28	59.32	b-Ala	220	10235	0.032	2.866		0.0
29	60.87	b-AlBA	494	16389	0.059	6.134		0.0
30	67.51	TTP	2063	115976	0.000	0.000		0.0
31	70.33	BOHMH2	470	32468	0.082	4.992		0.0
32	75.00		1046	128021	0.000	0.000		0.0
33	77.69	NH3	1300	201505	0.381	6.482		0.0
34	80.17		451	32728	0.000	0.000		0.0
35	82.31	Hylys	834	66555	0.106	17.227		0.0
36	85.96	Orn	34667	1202144	1.871	247.360		0.0
37	89.13	Lys	18259	920252	1.488	217.579		0.0
38	90.76		716	31753	0.000	0.000		0.0
39	94.65	His	3999	257737	0.421	65.400		0.0
40	98.36	3meHis	540	32384	0.054	9.185		0.0
41	101.77	Ans	130	12060	0.085	20.448		0.0
42	105.32	Car	276	24260	0.100	22.609		0.0
43	111.00	Arg	2514	148595	0.270	46.951		0.0
			412020	14451941	94.976	6835.097		

Peak rejection level: 10000

1.18922

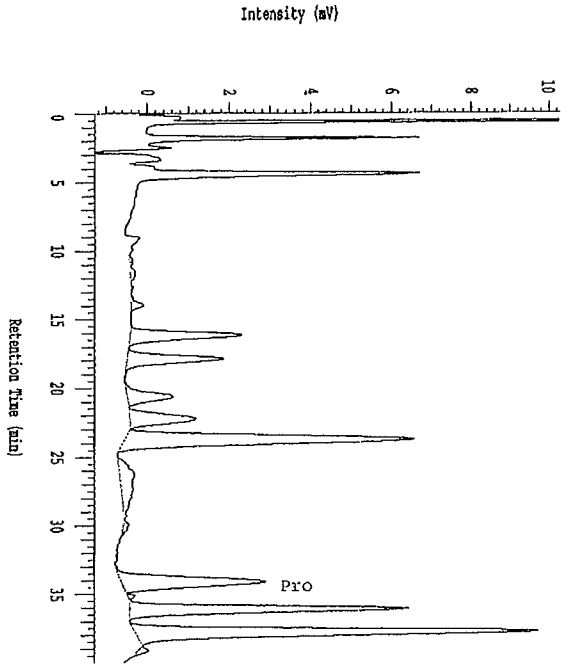
EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF Series: 0020 Report Name: original

Analized: 02:38 PM I-880 AAA System Manager Report Reported: 04:34 PM

Chrom Type: AAA Channel : 2

Series: 0020
Vial Number: 42
Vial Type: UNK
Volume: 20.0 uL
Injection from this vial: 1 of 1
Sample Name: 68.2
Sample Description: 68.2, 10:00
Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	16.16		2747	98713	0.000	0.000	0.0
2	17.89		2370	89239	0.000	0.000	0.0
3	20.61		1133	49868	0.000	0.000	0.0
4	22.23		1637	75165	0.000	0.000	0.0
5	23.76		7132	309480	0.000	0.000	0.0
6	26.31		375	55619	0.000	0.000	0.0
7	34.11	Pro	3535	166349	1.431	164.662	0.0
8	36.12		6888	220556	0.000	0.000	0.0
9	37.79		10029	355008	0.000	0.000	0.0
			35846	1419997	1.431	164.662	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF
Channel 1 Noise: 3 uV
Channel 1 Drift: 11 uV

Series: 0020

Report Name: original
Channel 2 Noise: 21 uV
Channel 2 Drift: 9 uV

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0033

Report Name: original

Activity: 0.6423

L-8800 AAA System Manager Report

Analyzed: 06:33 AM

Series: 0033

Sample Name: 76.2

Injection from this vial: 1 of 1

Reported: 08:30 AM

Vial Number: 48

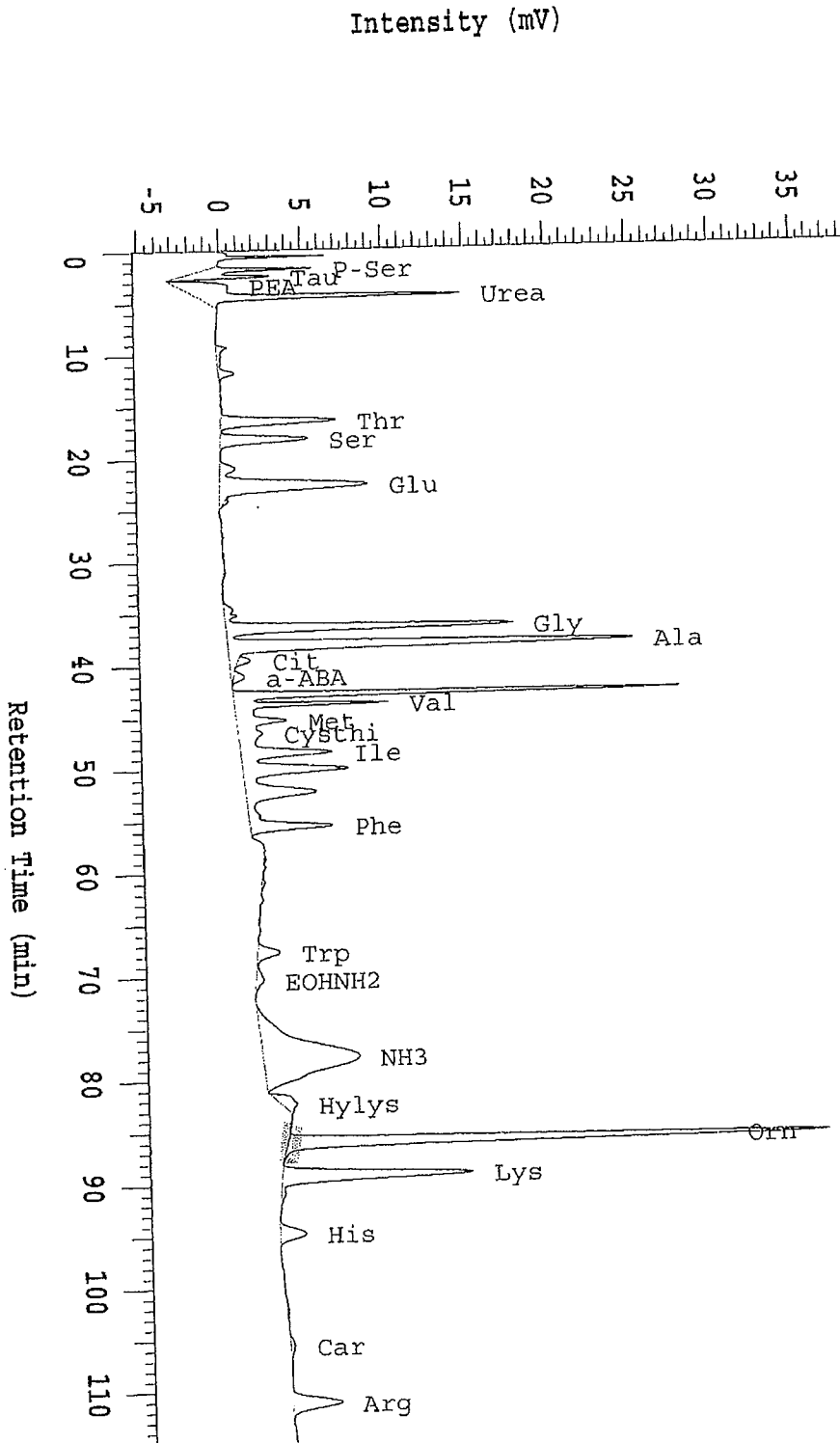
Vial Type: UNK

Volume: 20.0 ul

Sample Description:

76.2, 10:00, t=30

Chrom Type: AAA Channel: 1



Peak rejection level: 10000

Page Indicator: 17

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0033

Report Name: original

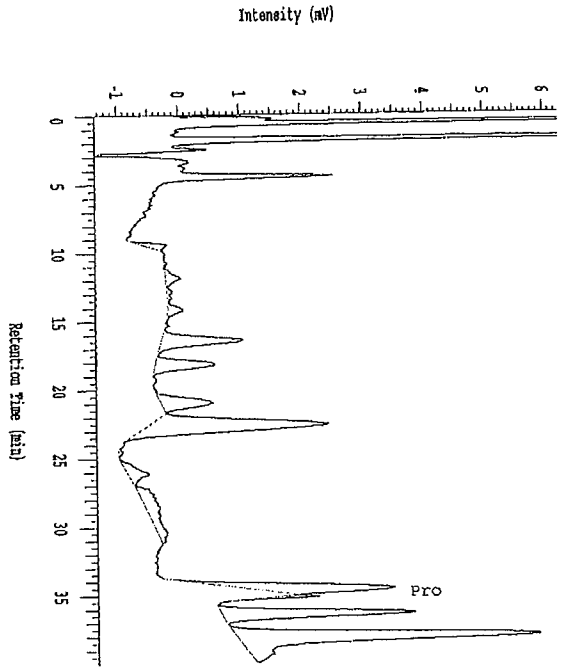
L-8800 AA System Manager Report

Analyzed: 06:33 AM

Reported: 08:30 AM

Chrom Type: AAA Channel : 2

Series: 0033
Vial Number: 48
Vial Type: UNK
Volume: 20.0 uL
Injection from this vial: 1 of 1
Sample Name: 76.2
Sample Description: 76.2, 10:00, t=30
Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	11.88		260	10061	0.000	0.000	0.0
2	16.40		1336	55024	0.000	0.000	0.0
3	18.21		986	41763	0.000	0.000	0.0
4	21.00		859	39376	0.000	0.000	0.0
5	22.61		2956	163707	0.000	0.000	0.0
6	26.15		353	19085	0.000	0.000	0.0
7	30.39		175	41895	0.000	0.000	0.0
8	34.63	Pro	2309	92243	0.870	100.159	0.0
9	36.43		3164	109747	0.000	0.000	0.0
10	38.12		5006	234875	0.000	0.000	0.0
			17404	807776	0.870	100.159	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0033

Report Name: original Activity = 0.0446

L-8800 AAA System Manager Report

Analyzed: [REDACTED]

04:29 PM

Reported: [REDACTED]

06:25 PM

Series: 0033

Vial Number: 52

Sample Name: [REDACTED]

Vial Type: UNK

Injection from this vial: 1 of 1

Volume: 20.0 ul

Sample Description: [REDACTED]
10:00, t=30

Chrom Type: AAA Channel : 1

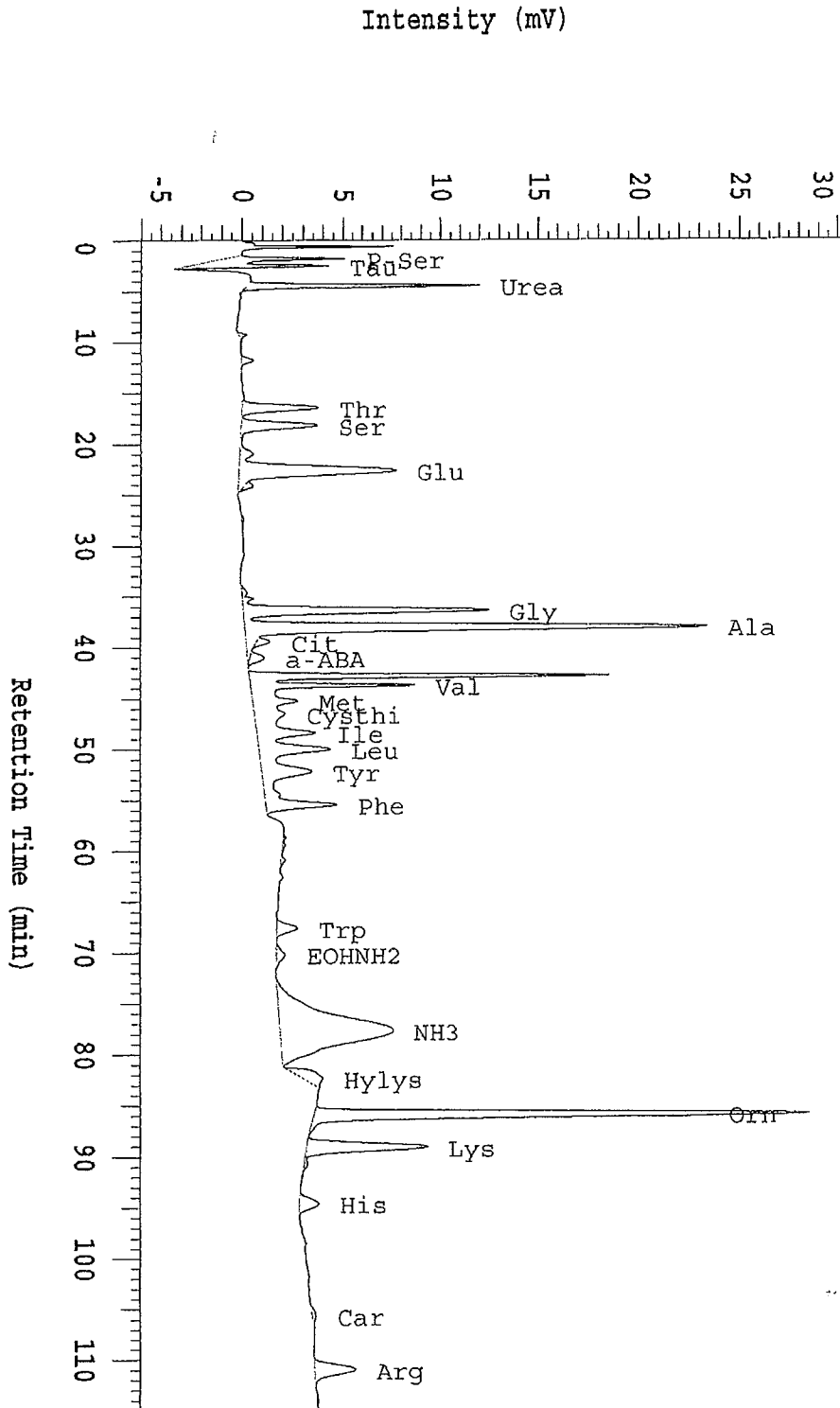


EXHIBIT B **USSN 10/518,223**

Peak rejection level: 10000

L-8800 ASM: PF		Series: 0033		Report Name: original				
Analyzed:	04:29 PM	Vial Number: 52		Sample Name: [REDACTED]				
Reported:	06:25 PM	Volume: 20.0 uL		Vial Type: UNK				
No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Scale Factor 1: 1.000	Peak Ratio
1	1.80	P-Ser	6004	115865	0.266	49.177		0.0
2	2.50	Tau	6993	126729	0.342	42.783		0.0
3	4.46	Urea	11822	232427	28.105	1689.096		0.0
4	11.76		603	20149	0.000	0.000		0.0
5	16.40	Thr	3790	156068	0.000	0.000		0.0
6	18.15	Ser	3766	168284	0.000	0.000		0.0
7	20.89		651	36752	0.000	0.000		0.0
8	22.60	Glu	7913	483815	0.000	0.000		0.0
9	24.08		442	15626	0.000	0.000		0.0
10	34.63		279	12101	0.000	0.000		0.0
11	35.16		587	14938	0.000	0.000		0.0
12	36.37	Gly	12465	448857	1.228	92.243		0.0
13	38.03	Ala	23224	977864	0.000	0.000		0.0
14	39.40	Cit	672	23548	0.000	0.000		0.0
15	40.97	a-ABA	704	33760	0.000	0.000		0.0
16	42.80		18195	409786	0.000	0.000		0.0
17	43.71	Val	8278	214474	0.489	57.330		0.0
18	45.24	Met	2244	120676	0.276	41.210		0.0
19	46.49	Cyschi	1539	130743	0.237	52.788		0.0
20	48.36	Ile	2894	164955	0.379	49.721		0.0
21	49.99	Leu	3551	221827	0.539	70.690		0.0
22	52.15	Tyr	2485	202816	0.517	93.605		0.0
23	54.44		797	35602	0.000	0.000		0.0
24	55.45	Phe	3538	163094	0.406	67.059		0.0
25	67.56	Tyr	1027	57152	0.000	0.000		0.0
26	70.12	BOHNR2	432	33411	0.102	6.253		0.0
27	77.67	NH3	5697	1157161	3.860	65.617		0.0
28	82.31	Hylys	1036	91209	0.230	37.291		0.0
29	85.93	Orn	24954	956409	2.270	300.141		0.0
30	89.08	Lys	6190	327966	0.842	123.150		0.0
31	94.55	His	980	66036	0.188	29.151		0.0
32	105.64	Car	195	14969	0.091	20.697		0.0
33	110.95	Arg	2096	138408	0.411	71.627		0.0
			166043	7373477	40.779	2959.628		

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0033

Report Name: original

L-8800 AA System Manager Report

Analyzed: 04:29 PM

Reported: 06:25 PM

Chrom Type: AAA Channel : 2

Series: 0033

Vial Number: 52

Vial Type: UNK

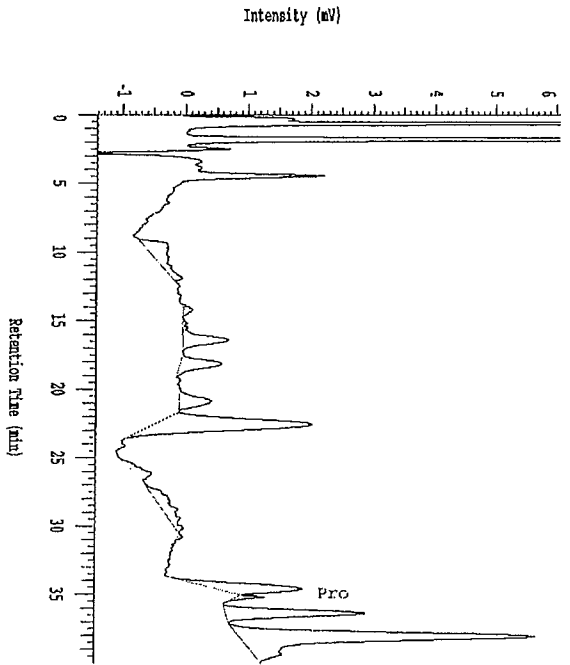
Volume: 20.0 ul

Injection from this vial: 1 of 1

Sample Name: 78.2

Sample Description: 78.2, 10:00, t=30

Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	11.88		181	38076	0.000	0.000	0.0
2	16.40		744	33472	0.000	0.000	0.0
3	18.12		668	29135	0.000	0.000	0.0
4	20.85		526	24601	0.000	0.000	0.0
5	22.57		2557	143037	0.000	0.000	0.0
6	26.15		283	15458	0.000	0.000	0.0
7	30.12	Pro	148	32797	0.000	0.000	0.0
8	34.60		1373	56985	0.538	61.876	0.0
9	36.37		2242	76355	0.000	0.000	0.0
10	38.05		4805	228349	0.000	0.000	0.0
			13527	678265	0.538	61.876	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0033

Report Name: original Activity = 0.0424

L-8800 AAA System Manager Report

Analyzed: 09:27 PM

Series: 0033

Sample Name: 79.2

Injection from this vial: 1 of 1

Reported: 11:23 PM

Vial Number: 54

Vial Type: UNK

Volume: 20.0 ul

Sample Description:

79.2, 10:00, t=30

Chrom Type: AAA Channel : 1

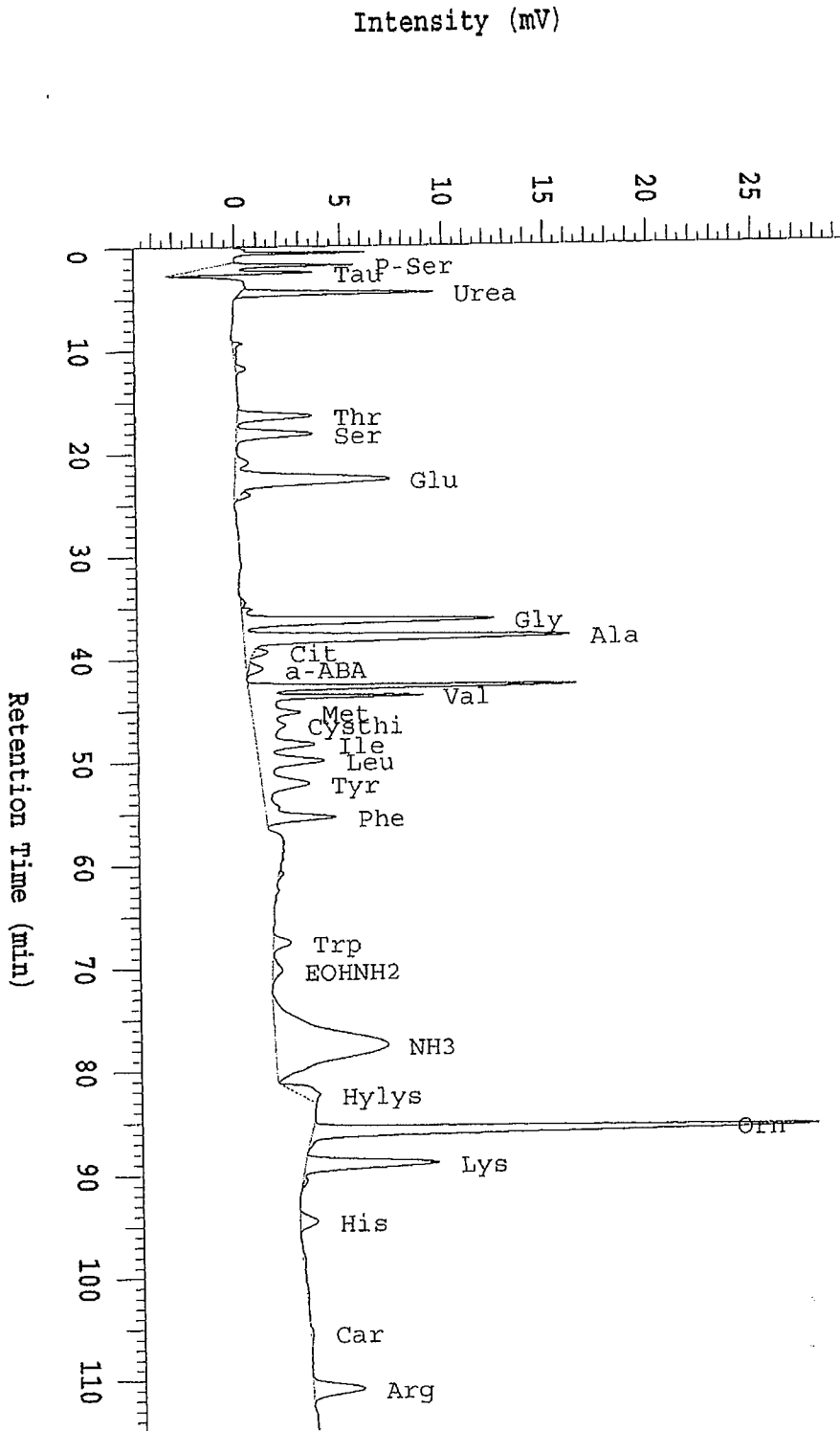


EXHIBIT B

USSN 10/518,223

L-8800 ASM: PF		Series: 0033		Report Name: Original			
Analyzed: 09:27 PM	Vial Number: 54	Sample Name: 79.2	Scale Factor 1: 1.000				
Reported: 11:23 PM	Volume: 20.0 u1	Vial Type: UNK					
No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	1.79	P-Ser	6489	121314	0.278	51.489	0.0
2	2.49	Tau	6328	115545	0.312	39.008	0.0
3	4.51	Urea	9321	198088	23.953	1439.547	0.0
4	9.35		550	24294	0.000	0.000	0.0
5	11.84		494	17834	0.000	0.000	0.0
6	16.43	Thr	3532	143649	0.000	0.000	0.0
7	18.17	Ser	3574	155814	0.000	0.000	0.0
8	20.96		601	31715	0.000	0.000	0.0
9	22.63	Glu	7400	450010	0.000	0.000	0.0
10	24.08		459	16080	0.000	0.000	0.0
11	35.19		514	10623	0.000	0.000	0.0
12	36.37	Gly	12191	434446	1.189	89.281	0.0
13	38.03	Ala	15834	671040	0.000	0.000	0.0
14	39.35	Cit	642	23387	0.000	0.000	0.0
15	40.99	a-ABA	676	31292	0.000	0.000	0.0
16	42.81		15978	363753	0.000	0.000	0.0
17	43.72	Val	8340	221370	0.505	59.173	0.0
18	45.24	Met	2321	116377	0.266	39.742	0.0
19	46.47	Cysthi	1518	128026	0.233	51.691	0.0
20	48.36	Ile	2800	158792	0.365	47.864	0.0
21	49.96	Leu	3138	193388	0.470	61.627	0.0
22	52.15	Tyr	2269	178704	0.455	82.477	0.0
23	54.47		721	34546	0.000	0.000	0.0
24	55.43	Phe	3321	153167	0.381	62.978	0.0
25	67.59	Trp	854	50684	0.120	7.356	0.0
26	70.33	BOHMH2	462	39301	0.000	0.000	0.0
27	77.72	NH3	5419	1087680	3.628	61.677	0.0
28	82.41	Hylys	979	90796	0.229	37.122	0.0
29	85.93	Orn	24591	942559	2.237	295.794	0.0
30	89.11	Lys	6550	347806	0.893	130.600	0.0
31	94.65	His	879	59486	0.169	26.259	0.0
32	105.48	Car	135	42321	0.259	58.514	0.0
33	111.00	Arg	2510	166324	0.494	86.074	0.0
Peak rejection level: 10000			151390	6820211	36.436	2728.273	

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0033

Report Name: original

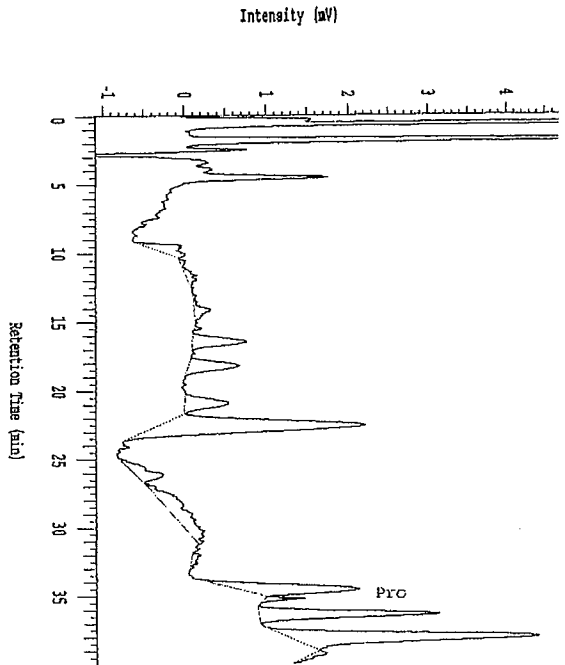
L-8800 AAA System Manager Report

Analyzed: 09:27 PM

Reported: 11:23 PM

Chrom Type: AAA Channel : 2

Series: 0033
Vial Number: 54
Vial Type: UNK
Volume: 20.0 u1
Injection from this vial: 1 of 1
Sample Name: 79.2
Sample Description: 79.2, 10:00, t=30
Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	10.13		191	17776	0.000	0.000	0.0
2	16.47		673	25853	0.000	0.000	0.0
3	18.19		636	25794	0.000	0.000	0.0
4	20.96		542	24702	0.000	0.000	0.0
5	22.56		2563	143003	0.000	0.000	0.0
6	26.11		350	19429	0.000	0.000	0.0
7	30.23		227	45358	0.000	0.000	0.0
8	34.56	Pro	1473	61933	0.584	67.248	0.0
9	36.37		2232	73775	0.000	0.000	0.0
10	38.04		3146	128070	0.000	0.000	0.0
			12033	565693	0.584	67.248	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0029

Report Name: original Activity: 0.0046

L-8800 AAA System Manager Report

Analyzed: 05:35 PM

Reported: 07:32 PM

Series: 0029

Vial Number: 23

Sample Name: 81.2

Vial Type: UNK

Injection from this vial: 1 of 1

Volume: 20.0 ul

Sample Description: 81.2, 1000,

t30/D=2

Chrom Type: AAA Channel: 1

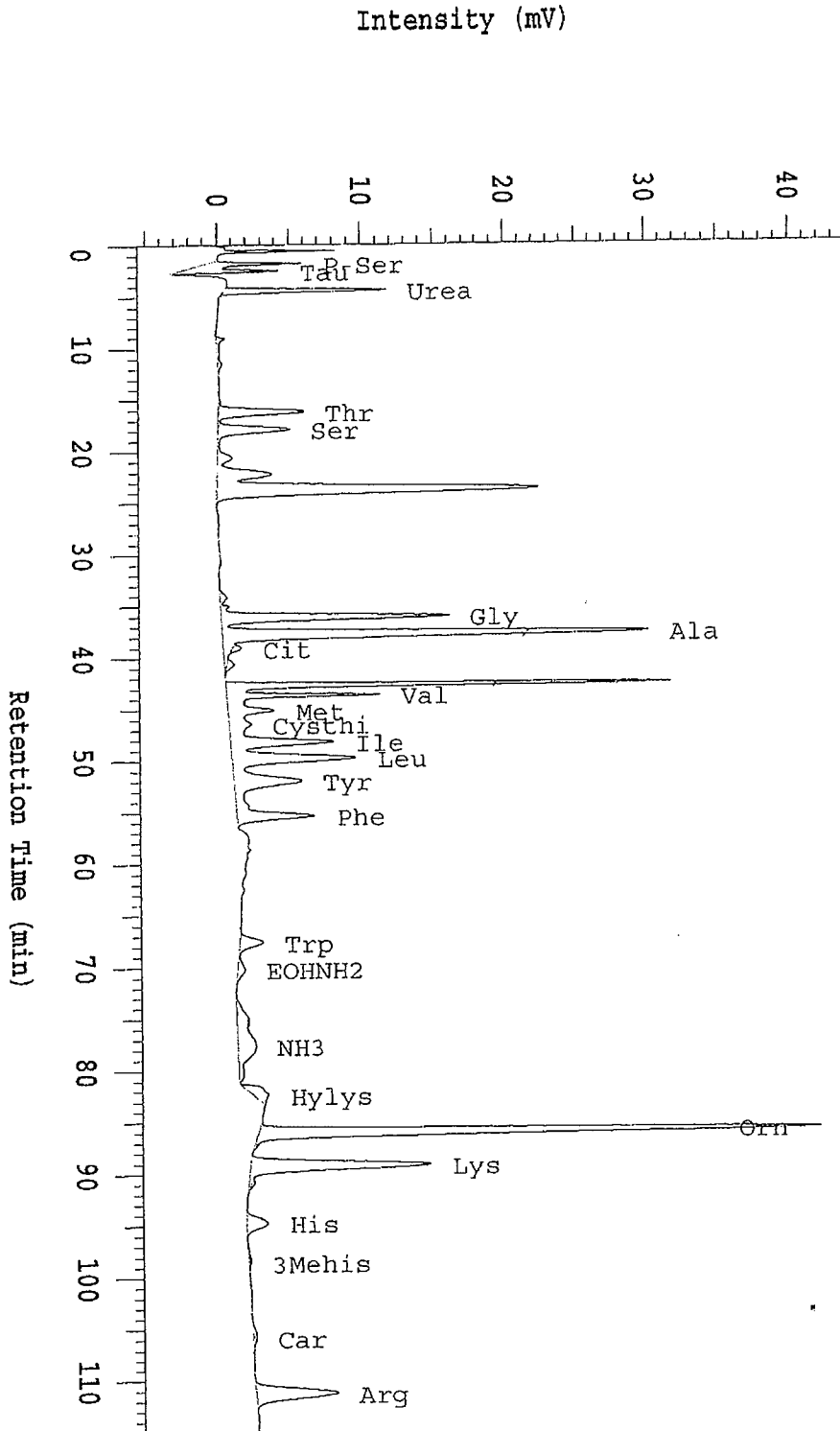


EXHIBIT B USSN 10/518,223

L-8800 ASM: PF									
Series: 0029									
Analyzed: 05:35 PM		al Number: 23		Sample Name: [REDACTED]		Report Name: original		81.2	
Reported: 07:32 PM		Volume: 20.0 ul		Vial Type: UNK		Scale Factor 1: 1.000			
No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio		
1	1.78	P-Ser	6590	124126	0.285	52.683	129.1		
2	2.49	Tau	6917	120628	0.325	40.723	134.2		
3	4.39	Urea	11356	217692	26.323	1582.016	104.7		
4	9.06		629	26079	0.000	0.000	0.0		
5	11.55		296	12486	0.000	0.000	0.0		
6	16.16	Thr	5997	240999	0.000	0.000	0.0		
7	17.85	Ser	5015	216753	0.000	0.000	0.0		
8	20.59		1048	56040	0.000	0.000	0.0		
9	22.20		3824	213377	0.000	0.000	0.0		
10	23.72		22530	1137804	0.000	0.000	0.0		
11	34.12		491	24642	0.000	0.000	0.0		
12	36.07	Gly	680	12955	0.000	0.000	0.0		
13	37.71	Ala	29956	561655	1.537	115.423	100.0		
14	39.04	Cit	662	1210138	0.000	0.000	0.0		
15	40.60		551	25938	0.000	0.000	0.0		
16	42.65		31257	646272	0.000	0.000	0.0		
17	43.63	Val	10669	245616	0.560	65.654	129.3		
18	45.08	Met	3270	152452	0.349	52.062	146.3		
19	46.41	Cyschi	1550	115052	0.209	46.453	258.4		
20	48.17	Ile	7192	329962	0.758	99.458	109.4		
21	49.75	Leu	8654	446133	1.084	142.169	104.7		
22	51.93	Tyr	4747	342289	0.872	157.976	111.6		
23	55.35	Phe	5421	295991	0.737	121.702	121.5		
24	67.56	Trp	1626	95191	0.000	0.000	0.0		
25	70.15	EOHNE2	519	43814	0.134	8.200	143.7		
26	75.00	NH3	826	94198	0.000	0.000	0.0		
27	77.53		1249	195495	0.652	11.086	84.5		
28	80.20		364	29582	0.000	0.000	0.0		
29	82.36	HVLYS	1066	96910	0.244	39.622	197.2		
30	85.96	OLET	39384	1479228	3.511	464.212	99.9		
31	89.19	Lys	12540	675295	1.734	253.570	104.3		
32	94.73	His	1485	102681	0.292	45.327	95.6		
33	98.55	3Methis	142	13218	0.037	6.192	139.4		
34	105.80	Car	215	19294	0.118	26.676	163.5		
35	111.24	Arg	5702	369721	1.098	191.333	99.4		
36									
Peak rejection level: 10000			250334	10011582	40.860	3522.537			

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0029

Report Name: original

L-8800 AA System Manager Report

Analyzed: 05:35 PM

Reported: 07:32 PM

Chrom Type: AAA Channel : 2

Series: 0029

Vial Number: 23

Vial Type: UNK

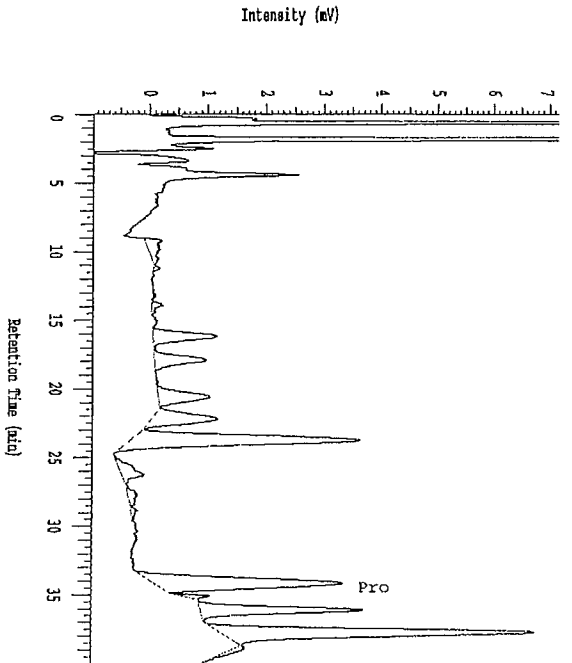
Volume: 20.0 u1

Injection from this vial: 1 of 1

Sample Name: 81.2

Sample Description: 81.2, 1000, t30,D=2

Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	9.16		302	17249	0.000	0.000	0.0
2	16.13		1116	43266	0.000	0.000	0.0
3	17.88		904	37340	0.000	0.000	0.0
4	20.53		899	42375	0.000	0.000	0.0
5	22.17		1144	55311	0.000	0.000	0.0
6	23.69		3962	184852	0.000	0.000	0.0
7	26.20		417	23111	0.000	0.000	0.0
8	34.12	Pro	3271	158058	1.491	171.623	93.2
9	36.08		2823	93152	0.000	0.000	0.0
10	37.72		5522	209789	0.000	0.000	0.0
			20360	864503	1.491	171.623	

Peak rejection level: 10000

EXHIBIT C
USSN 10/518,223

Mrs. [REDACTED]

Arginine concentration , umol

Sample	Time (hour)	Arginine (umol)
1	-24	44.6
3	-4	23.6
4	1	10.7
6	6	15
8	10	17.6
9	12	20.5
10	14	17.3
13	20	16.5
15	24	12.8
16	28	8.1
17	32	12.1
19	40	8.8
21	44	5
22	52	3.8
23	56	3.1
24	60	4.3
25	64	5.5
26	68	3.2
27	72	2.8
29	80	8.3
30	84	2.6
31	88	5.2
32	92	2.4
34	100	4.5
35	104	3.4
36	108	6.7
37	112	5.9
38	116	8.4
39	120	5.3
40	124	7.5
41	128	5.1
42	132	6.6
43	136	6.3
44	140	5.2
46	148	5.2
47	152	18.5
48	156	33.6
50	164	34.9
51	168	27.8
52	172	39.4
53	176	57

Sample	Time (hour)	Arginine (umol)
54	180	61.3
55	184	49.2
56	188	50.6
57	192	55.1
58	196	61.3
59	200	48.2
60	204	59.1
62	212	44.5
63	216	29.4
64	220	43.2
65	224	33.9
66	228	50.5
67	240	35.1
68	264	27.6
69	288	30.4
70	296	46.8
71	312	53
72	336	46.3
73	360	34.5
75	408	40
76	432	128.5
77	456	124.3
78	504	57.8
79	552	96.7
80	624	82.8
81	672	133.5

EXHIBIT D
USSN 10/518,223

Mrs [REDACTED]
Activity Tests

Sample	Time / hour	Activity / min
4.2	1	0.083
7.2	8	0.036
11.2	16	0.064
15.2	24	0.049
17.2	32	0.093
19.2	40	0.083
21.2	48	0.106
23.2	56	0.133
25.2	64	0.109
28.2	76	0.113
30.2	84	0.096
31.2	88	0.093
33.2	96	0.09
35.2	104	0.107
37.2	112	0.084
39.2	120	0.115
41.2	128	0.135
43.2	136	0.082
45.2	144	0.106
49.2	160	0.057
51.2	168	0.044
52.2	172	0.046

Sample	Time / hour	Activity / min
53.2	176	0.036
* 56.2	188	0.046
57.2	192	0.05
58.2	196	0.035
59.2	200	0.04
63.2	216	0.0427
64.2	220	0.0429
66.2	228	0.0455
* 67.2	240	0.0404
* 68.2	264	0.042
69.2	288	0.0575
70.2	296	0.05
71.2	312	0.046
72.2	336	0.05
73.2	360	0.05
75.2	408	0.0598
* 76.2	432	0.0433
77.2	456	0.0484
* 78.2	504	0.0446
* 79.2	552	0.0424
80.2	624	0.0408
* 81.2	672	0.0256